In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 19-89V
Filed: March 8, 2022
UNPUBLISHED

MATTHEW DOYE and RENEE DOYE, parents and natural guardians of J.R.D., on behalf of J.R.D.,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Influenza Vaccine; Guillain-Barre Syndrome (GBS); Table Injury; Factors Unrelated to Vaccination

Robert Thomas Dassow, Hovde Dassow & Deets, LLC, Indianapolis, IN, for petitioner.
Tyler King, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On January 17, 2019, petitioners filed a petition on behalf of their minor child under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012),[2] alleging that the influenza ("flu") vaccine she received on November 4, 2013, caused her to suffer Guillain-Barre Syndrome ("GBS"). (Pet., p. 1.) For the reasons set forth below, I conclude that petitioners are not entitled to compensation.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In

[1] Because this decision contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

[2] Within this decision, all citation to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a causal link between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless the government affirmatively shows that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B). As relevant here, the Vaccine Injury Table lists Guillain-Barre Syndrome or "GBS" as a compensable injury if it occurs between three and 42 days of the flu vaccination in question. 42 C.F.R. § 100.3 (2022).

The Vaccine Act states that:

> [F]actors unrelated to the administration of the vaccine . . . may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

§ 300aa-13(a)(2)(B).

In the Vaccine Injury Compensation Program, petitioners must establish a *prima facie* claim to entitlement by preponderant evidence. *De Bazan v. Sec'y of Health & Human Servs.*, No. 03-0620V, 2006 WL 5616948 at * 1 (Fed. Cl. Spec. Mstr. Jun. 30, 2006); *see also* §300aa-13(a)(1)(A). Once a petitioner has established their *prima facie* case, the burden then shifts to respondent to prove, also by preponderant evidence, that the alleged injury was caused by a factor unrelated to vaccination. *See id.; see also* § 300aa-13(a)(1)(B).

II. Procedural History

Petitioners filed their petition on January 17, 2019, alleging that their minor daughter developed GBS as a result of a flu vaccination that she received on November 4, 2013. (ECF No. 1.) The following day, this case was assigned to the Court's Special Processing Unit ("SPU") and petitioners filed a series of medical records in support of their petition. (ECF Nos. 4, 6.) On October 3, 2019, respondent filed his rule 4(c) report recommending against compensation and an expert report by infectious disease

specialist Dr. Haley Gans opining that J.R.D's GBS was more likely than not caused by a viral infection. (ECF Nos. 16, 17.) This case was reassigned to my docket on October 7, 2019. (ECF No. 19.) On October 11, 2019, I suspended petitioner's deadline to file an expert report and ordered them to file the outstanding medical records identified in respondent's Rule 4 report within 30 days. (ECF No. 20.)

Petitioners failed to file their outstanding medical records by November 18, 2019, at which point I issued a *sua sponte* order extending their deadline. (NON-PDF Scheduling Order filed on 11/18/2019.) Petitioners filed several motions for extensions of time to file these records between late November and late January before ultimately filing their outstanding medical records on February 28, 2020. (ECF Nos. 21-26.) On March 11, 2020, I set a 60-day deadline for petitioners to file an expert report supporting their claim and responding to respondent's Rule 4 report. (NON-PDF Scheduling Order filed on 3/11/2020.) After two deadline extensions, petitioners filed a report from Dr. Thomas Slama on August 10, 2020. (ECF Nos. 27, 28, 31.) Dr. Slama's report did nothing more than restate the existing medical record and make a conclusory statement, with no analysis whatsoever, that J.R.D.'s GBS was caused by her flu vaccination. (ECF No. 31.) Dr. Slama failed to address any of the points raised in Dr. Gans's report. (*Id.*)

On August 11, 2020, I issued a scheduling order again directing petitioners to file an additional expert report due to the fact that Dr. Slama's report was "facially inadequate for a number of reasons and fail[ed] to meaningfully respond to respondent's expert presentation." (ECF No. 32.) After several motions for an extension of time and a status conference discussing petitioners' difficulties in securing an expert report, petitioners filed a notice on September 3, 2021, informing the Court that they were unable to secure an additional expert report, and would rely only on Dr. Slama's report. (ECF Nos. 33-35, 37, 38.) Following petitioners' notice that they would not be submitting an additional expert report, I issued a scheduling order directing the parties to file briefs supporting their respective positions. (ECF No. 39.) Respondent filed the present motion for a ruling on the record on October 7, 2021. (ECF No. 40.) Petitioners did not file any response or otherwise submit any written brief in support of their claims.

I have provided petitioner a full and fair opportunity to present their case and develop the record, including the opportunity to present a written submission. Accordingly, this case is now ripe for a ruling on the written record. *See* Vaccine Rule 3(b)(2); Vaccine Rule 8(d).

III. Factual History

a. As reflected in the medical record

Prior to her vaccination, petitioners' daughter, J.R.D., was a relatively healthy six-year-old with a history of post-viral 6th central nerve palsy during infancy and developmental delay. (Ex. 2, pp. 11, 105.) Prior to the vaccination in question, J.R.D.

had received 13 other influenza vaccinations along with other typical childhood vaccines. (*Id.* at 2, 19.) On November 4, 2013, she received a Flumist vaccine at her pediatrician's office. (*Id.* at 18.) J.R.D.'s parents called her pediatrician on November 19, 2013 because J.R.D. had a "subnormal" temperature of 95.5 degrees following a gastrointestinal illness that occurred about a week and a half prior. (*Id.*) Petitioners noted that J.R.D. exhibited nausea and vomiting during this period, but that she had since recovered. (*Id.*) Petitioners reported that J.R.D. awoke at 6 AM that day complaining that she was unable to walk to the bathroom due to weakness in her legs and knees. (*Id.*) J.R.D.'s mother reported that her daughter slept all day with no food or fluids, appeared agitated, and exhibited rapid, shallow breathing resembling panting. (*Id.*) J.R.D. was referred to the ER for further evaluation. (*Id.*)

J.R.D. was admitted to the Indiana University North Hospital emergency room during the evening of November 19, 2013. (Ex. 3, p. 51.) The history of present illness noted that J.R.D. was experiencing weakness, fatigue, lethargy, vomiting, and the inability to walk. (*Id.* at 53.) J.R.D. was initially diagnosed with a urinary tract infection and given IV fluids and antibiotics before being discharged. (*Id.*) J.R.D. was brought back to the ER early the next morning at 1:41 AM with a decreased mental state, "unpurposeful movements", truncal ataxia, and decreased respiratory drive. (*Id.* at 47.) The attending physician recommended intubation, testing for suspected viral encephalitis, warming, continued fluids, and sedation. (*Id.*) J.R.D. was transferred to the pediatric intensive care unit later that morning. (*Id.* at 47.)

J.R.D. was seen by Dr. Laura Pacholski after she was transferred to the PICU on November 20, 2013. (Ex. 3, p. 544.) Her history of present illness indicated that J.R.D. went to her parents room around 6:30 AM on November 19 complaining that her legs "felt wobbly." (*Id.*) J.R.D. was said to have slept all day and only wake for very short periods before going back to sleep. (*Id.*) She showed no signs of fever, diarrhea, upper respiratory infection, trauma, or rash. (*Id.*) She was brought to the ER that evening for "persistent lethargy," and "foul smelling urine." (*Id.*) Petitioner's family had recently been sick with a gastrointestinal illness, and a urine culture from the previous day returned positive for E.Coli. (Ex. 3, pp. 88-89.) J.R.D.'s CSF studies were normal, but borderline, and a brain MRI revealed an "old shear injury causing scarring in [the] corpus callosum," but no reported signs of encephalitis. (*Id.* at 27, 30, 543.) The treating physicians believed Guillain-Barre Syndrome ("GBS") was a possibility based on J.R.D.'s borderline protein levels, the temporal proximity of onset to her recent flu shot, and her persistent weakness. (*Id.* at 27.)

J.R.D. was seen by neurologist Dr. Lan Chen at the PICU on November 20, 2013. (Ex. 3, p. 550.) Dr. Chen recorded a history of flu-like symptoms, vomiting, acute onset of muscle weakness, and rapid deterioration of respiratory status. (*Id.*) A record from Dr. Chen on November 21 indicates that J.R.D.'s brain and spinal MRIs were normal, but her EMG nerve conduction was "borderline abnormal with subtle decrease of conduction rate." (*Id.* at 549) Her CSF showed a protein of 47, but she responded to commands and communicated through blinking. (*Id.*) J.R.D.'s mother noted that she was reading to her daughter and watching TV with her, and that J.R.D.

appeared to understand what she saw and heard but seemed sleepy. (*Id.*) J.R.D.'s mother also described her muscle strength as having decreased from the previous day. (*Id.*) On physical examination, J.R.D. exhibited no obvious ptosis, reactive pupils with one larger than the other, deep tendon reflexes in both biceps but none in her lower extremities, and no obvious sensory symptoms. (*Id.*) Dr. Chen noted that there was no imaging or electrophysiological evidence supporting a finding of GBS, but that it was nonetheless "the top of differential diagnosis." (*Id.*) Dr. Chen recommended that J.R.D. continue to receive IVIG, undergo an additional EMG Nerve conduction study, and considered a lumbar puncture and cervical MRI if she showed no signs of improvement. (*Id.*)

On November 23, 2013, J.R.D. showed worsening motor function involving multiple cranial nerves. (Ex. 3, p. 563.) A neurology progress note indicated that "GBS, possibly axonal form is high on [the] differential diagnosis list." (*Id.*) J.R.D. was subsequently transferred to Riley Children's Hospital ("RCH") Pediatric Intensive Care Unit ("PICU") for plasmapheresis. (*Id.* at 566.) The medical history taken at RCH is consistent with that reported to the emergency department and Dr. Chen, stating that on November 19, 2013, J.R.D. exhibited signs of lower extremity and trunk weakness, respiratory issues, vomiting, and ptosis. (Ex. 2, pp. 63-64.) J.R.D.'s admitting physician at RCH noted that she showed risk factors for GBS, including her flumist vaccine, gastrointestinal illness, and possibly Botulism. (*Id.* at 67.) J.R.D. was subsequently intubated due to respiratory distress; the PICU scheduled her for plasmapheresis, botulism testing, a lumbar puncture, brain and spine MRIs, and consults with neurology and genetics. (*Id.*) J.R.D.'s lumbar puncture showed an elevated protein of 161 with some evidence suggestive, but not conclusive, of a prior or developing mycoplasma pneumoniae infection. (Ex. 4, p. 30; Ex. 15, p. 37; *see* Ex. 2, p. 95.) J.R.D. received five rounds of plasmapheresis therapy and was subsequently extubated on December 4, 2013. (Ex. 15, pp. 37-43.) She was discharged on December 8, 2013 and admitted to inpatient rehabilitation on December 18, 2013 until January 17, 2014. (*Id.*; Ex. 9, p. 32.) J.R.D. received physical, occupational, speech, and swallow therapy during her admission, and by the time she was discharged, could write her name, dress her upper body, put on and take off shoes, fasten buttons, and was eating and drinking a regular diet without difficulty. (Ex. 9, pp. 32-34.) J.R.D. continued to attend outpatient physical therapy once a week after her discharge. (Ex. 5, pp. 20-28.) As of February 26, 2014, she was able to ride a bike and climb stairs without assistance. (*Id.*)

On February 27, 2014, J.R.D. saw neurologist Dr. Mandy Harris for a follow up on her GBS. (Ex. 4, p. 6.) J.R.D. was reported to have been waking frequently at night, showing some aggression at school, and exhibiting different sized pupils. (*Id.*) J.R.D.'s examination was otherwise unnoteworthy aside from +1 deep tendon reflexes. (*Id.*) Ultimately, Dr. Harris noted that J.R.D. was "recovering wonderfully." (*Id.*)

J.R.D. returned to her pediatrician Dr. Susan Davis on March 21, 2014. (Ex. 2, p. 19.) At this time, she had returned to school and was reported to be doing "really well." (*Id.*) On April 11, 2014, J.R.D. was seen by Dr. Michelle E. Howenstine for a follow up on her earlier hospitalization. (Ex. 15, p. 27-28.) Dr. Howenstine found no "significant

respiratory symptoms" and recommended J.R.D. return in one year for an additional follow up. (*Id.* at 28.) J.R.D. was again seen by Dr. Davis on April 25, 2014 with a chief complaint of fever. (Ex. 2, p. 20.) Dr. Davis noted J.R.D.'s history of GBS but did not recommend any treatment. (*Id.*)

J.R.D. was seen by Dr. Kerstin Sobus for follow up at Pediatric Physical Medicine & Rehabilitation on April 30, 2014. (Ex. 6, p. 2.) J.R.D. was able to walk, exhibited normal gait, and had 4/5 strength. (*Id.* at 3-4.) Dr. Sobus recommended that J.R.D. participate in physical activities such as swim lessons to facilitate her recovery and that formal rehabilitation may no longer be necessary. (*Id.* at 4.)

J.R.D. returned to Dr. Harris for a neurology follow up on December 4, 2015. (Ex. 4, pp. 3-4.) J.R.D. exam was normal aside from the fact that her right pupil remained larger than her left. (*Id.*) She was noted to be "completely recovered." (*Id.*) The most recent record in J.R.D.'s medical record is a March 30, 2017 wellness visit where she was noted to be doing well aside from some speech concerns and anisocoria of the eyes. (Ex. 15, p. 11.)

b. As reflected in the affidavit of Matthew Doye

J.R.D.'s father, Matthew Doye submitted an affidavit alongside the medical records in this case. (Ex. 8.) Mr. Doye's affidavit focuses primarily on the onset of J.R.D.'s condition and less on her subsequent recovery. It does not differ substantively from what is recorded in J.R.D.'s medical records as described above.

IV. Expert Opinions

a. Petitioner's Expert Dr. Thomas Slama

Petitioners filed an affidavit from Dr. Thomas Slama[3] in support of their claim. (ECF No. 31.) The majority of Dr. Slama's affidavit simply restates facts found in the medical record. After reviewing the medical record, Dr. Slama concludes without any reference to medical literature, medical theory, or any medical analysis whatsoever, that J.R.D.'s GBS "could possibly have been exacerbated by the influenza vaccine." (ECF

[3] Dr. Slama received his bachelor's degree in 1969 and medical degree in 1973 both from Indiana University. (ECF No. 31-2, p. 1.) He completed his residency in internal medicine at Methodist Hospital in Indianapolis, Indiana and a fellowship in infectious diseases at the Ohio State University School of Medicine from 1973 to 1976. (*Id.*) Dr. Slama then went on to receive a master's degree in medical microbiology in 1978. (*Id.*) He has served as a clinical instructor at the Ohio State College of Medicine and held positions as an assistant, associate, and full professor of medicine at Indiana University School of Medicine from 1980 to 2014. (*Id.* at 2.) He served as a consulting physician at the Columbus Health Department Venereal Disease Clinic from 1976 to 1978, and as an active member of the Department of Infectious Disease at St. Vincent Hospital in Indianapolis from 1976 to 2014 where he also served as chief of the Division of Infectious Diseases from 1978 to 1998. (*Id.*) Dr. Slama also worked at the Human Hospital for Women as a consultant on infectious diseases and served as chairman of the Hospital's department of medicine from 1983 to 1985. (*Id.*) Dr. Slama is licensed by the state of Indiana and has published 72 pieces of medical literature focusing primarily on infectious diseases. (*Id.* at 5, 22-27.)

No. 31, p. 3.) This submission offers virtually no support to petitioner's claim beyond what is reflected in the medical records.[4]

b. Respondent's Expert Dr. Hayley Gans

Respondent filed a report from Dr. Hayley Gans[5] in support of his position. (Ex. A.) Dr. Gans begins her report by reviewing her qualifications and J.R.D.'s medical record in significantly more depth than Dr. Slama. (*Id.* at 1-2.) She then discusses GBS generally, noting that it "is the most common cause of acute flaccid paralysis in healthy infants and children." (*Id.* at 2.) She explains the symptoms of GBS, including progressive weakness over a period of hours to days, ascending from the lower to upper extremities and involving respiratory muscles in some cases. (*Id.* at 2.) She explains that pain and refusal to walk are commonly seen in children with GBS, along with cranial neuropathies, nerve palsies, and autonomic dysfunction. (*Id.* at 3.) Dr. Gans notes that the peak age for pediatric GBS patients is 5 to 6 years old and onset occurs more often during the cold months. (*Id.* (citing Rudolf Korinthenberg et al., *Clinical presentation and course of childhood Guillain-Barre syndrome: a prospective multicentre study,* 38 NEUROPEDIATRICS 10 (2007) (Ex. A.1).) Dr. Gans confirms that J.R.D.'s clinical course was consistent with GBS in children. (Ex. A, p. 3.)

Dr. Gans then discusses the etiology of GBS, noting that it has been shown to be preceded by infection in roughly 75% of all studied cases compared to control cohorts, with an increased risk in cases with preceding respiratory infections and gastroenteritis. (*Id.* (citing Korinthenberg et al., *supra*, at Ex. A.1; S.C. Melnick and T.H. Flewett, *Role of infection in the Guillain-Barre syndrome*, 27 J. OF NEUROLOGY, NEUROSURGERY, AND PSYCHIATRY 395 (1964) (Ex. A.2).) Dr. Gans writes that studies have found Campylobacter jejuni (C.jejuni) as the most common bacterial infection linked to GBS, and Cytomegalovirus (CMV) as the most common viral infection. (Ex. A p. 3.) In the studies finding a preceding gastroenteritis before GBS onset, the gastroenteritis occurred at most a week before onset of GBS, while respiratory illnesses linked to GBS typically occurred two weeks prior to onset. (*Id.*) GBS caused by C.Jejuni was found to cause more severe and longer lasting GBS cases, while studies focusing on CMV

[4] Even if Dr. Slama's opinion was not conclusory, his seeming equivocation, stating the vaccine "could possibly" have contributed to the GBS would also be problematic to petitioner's case. The mere possibility of vaccine causation is not strong evidence. *E.g. Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1360 (Fed. Cir. 2019) (citing *Moberly ex rel. Moberly*, 592 F.3d 1315 (Fed. Cir. 2010) ("We have consistently rejected theories that the vaccine only likely caused the injury and reiterated that a plausible or possible causal theory does not satisfy the standard.") (internal quotations omitted)).

[5] Dr. Gans received her bachelor's degree in biochemistry from Connecticut College in 1987 and her medical degree from The State University of New York Health Science Center in 1991. (Ex. B, p. 1.) She completed her medical internship and residency in pediatrics at the Stanford University School of Medicine from 1991 to 1994, and a fellowship in pediatric infectious diseases at Stanford from 1994 to 1998. (*Id.*) Dr. Gans served as a clinical instructor and research associate at Stanford from 1998 to 2004 before being promoted to clinical educator for the year of 2005. She later served as an acting, assistant, and clinical associate professor at Stanford from 2006 to present. (*Id.* at 2.) Dr. Gans is licensed by the state of California and has published 27 pieces of medical literature on immunology, genetics, biochemistry, and infectious diseases. (*Id.* at 4-5.)

revealed a younger cohort with higher rates of respiratory failure and cranial nerve palsies similar to what J.R.D. experienced. (*Id.* (citing Jeremy H. Rees et al., *Campylobacter Jejuni Infection and Guillain-Barre Syndrome*, 333 (21) NEW ENG. J. OF MED. 1374 (1995) (Ex. A.4); L.H. Visser et al., *Cytomegalovirus infection and Guillain-Barre syndrome: the clinical, electrophysiologic, and prognostic features*, 47 NEUROLOGY 668 (1996) (Ex. 4.5).) Thus, Dr. Gans concludes, that J.R.D.'s "preceding viral gastroenteritis, one week before the onset of GBS, the severity of her disease, and the diagnostic work up showing serologic evidence of mycoplasma infection," are all consistent with cases of GBS following infection. (*Id.*)

Dr. Gans then turns to GBS following immunizations, noting that "there have been several case reports and small studies showing an increase in GBS cases following influenza vaccine," but explaining that the reports "have difficulty assessing these cases in the background of influenza illness which is highly associated with GBS and other infections." (Ex. A, p. 3.) Dr. Gans opines that only studies positioned to observe an entire cohort while considering background rates in control cohorts are suited to evaluate the link between GBS and flu vaccines. (*Id.*) Dr. Gans cites a study conducted through the Vaccine Safety Datalink observing over 9 million members, approximately 1.3 million doses of the monovalent influenza vaccine and 2.8 million doses of the trivalent influenza vaccine which found no statistically significant link between the flu vaccines and GBS. (Ex. A, p. 3 (citing Sharon K. Greene et al., *Guillain-Barre Syndrome, Influenza Vaccination, and Antecedent Respiratory and Gastrointestinal Infections: A Case-Centered Analysis in the Vaccine Safety Datalink, 2009-2011*, 8(6) PLOS ONE e67185 (2013) (Ex. A.10).) Further, Dr. Gans writes that the first dose of a flu vaccine "is the immunologically plausible dose that would lead to new antibodies that would perhaps cross-link with neuronal proteins," causing GBS. Further, because J.R.D. had received multiple prior doses of influenza vaccine, Dr. Gans concludes that it is unlikely that J.R.D.'s most recent dose would be the one to cause her GBS. (Ex. A, p. 3.) Dr. Gans also notes that researchers have searched for potential links between the flumist vaccine that J.R.D. received and GBS, but were unable to find a statistically significant association. (Ex. A, p. 4 (citing Sirarat Sarntivijai et al., *Ontology -Based Combinatorial Comparative Analysis of Adverse Events Associated with Killed and Live Influenza Vaccines*, 7(11) PLOS ONE e49941 (2012) (Ex. A.11).)

Dr. Gans concludes her report by writing that there is little evidence supporting a link between the flumist vaccine and GBS, while there is significant evidence supporting a link between infection and GBS. (Ex. A, p. 4.) Because, J.R.D.'s medical records reveal that she suffered from gastroenteritis, a flu-like illness, and a possible mycoplasma infection shortly before onset of her GBS, Dr. Gans concludes that J.R.D.'s GBS was likely not caused by her flu vaccination, and more likely explained by these preceding infections. (*Id.*)

V. Discussion

As stated above, petitioners satisfy the requirements for a GBS Table Injury if they establish that onset of J.R.D.'s GBS occurred more than 3, but less than 42 days after her influenza vaccination so long as there is not preponderant evidence showing that J.R.D.'s GBS was the result of factors unrelated to her vaccination such as a preceding viral infection. *See* § 300aa-13(a); 42 C.F.R. § 100.3. Here, J.R.D.'s medical records preponderantly establish a *prima facie* showing of a GBS Table Injury. However, respondent is ultimately persuasive in meeting his shifted burden by preponderantly establishing that J.R.D.'s GBS was caused by factors unrelated to her vaccination.

J.R.D. received her influenza vaccination on November 4, 2013. (Ex. 2, p. 18.) Petitioners brought J.R.D. to the ER on November 19, 2013, with complaints of lower extremity weakness, reporting that she had recently experienced "flu like symptoms" and a gastrointestinal illness around "a week and a half" earlier. (*Id.*) The day after J.R.D. was admitted to the ER, she tested positive for E.Coli, and on November 22, 2013, her serology labs showed IgG and IgM antibody levels suggestive of a potential mycoplasma infection.[6] (Ex. 3, pp. 88-89, 95.) J.R.D.'s treating physicians noted that her GBS could also have been caused by botulism or her previous GI illness. (Ex. 2, p. 67.)

Respondent's expert explained that 75% of studied GBS cases were found to occur following a viral or bacterial infection, with increased risk of GBS specifically linked to respiratory infections and gastroenteritis. (Ex. A, p. 3 (citing Korinthenberg et al., *supra*, at Ex. A.1; Melnick & Flewett, *supra,* at Ex. A.2).) Further, in cases of GBS involving a preceding gastroenteritis, the infection typically occurred a week prior to onset of GBS symptoms. In cases with a preceding respiratory infection, the infection occurred two weeks prior. (Ex. A, p. 3.) Here, J.R.D. was reported to have suffered a gastrointestinal illness and flu-like symptoms a "week and a half" prior to onset of her GBS symptoms. (Ex. 2, p. 18; Ex. 3, p. 550.) These conditions could both be responsible for J.R.D.'s GBS according to Dr. Gans. (Ex. A, p. 4.) Further, J.R.D.'s serology labs were suggestive of a mycoplasma pneumoniae infection. (Ex. 3, p. 95.) Finally, Dr. Gans opines that if an individual were to develop GBS due to a vaccination, it is more likely the first dose of the vaccine would trigger onset of GBS. (Ex. A, p. 4.) However, Dr. Gans points out in her report that J.R.D. received many prior flu vaccine doses prior to the dose in question, lending further support to the contention that J.R.D.'s GBS was the result of a factor unrelated to her vaccination. (Ex. A, p. 4; *see also* Ex. 2, p. 2, 19.)

[6] The serology report notes that IgM and IgG antibodies are "reactive but NOT diagnostic," and that diagnosis must be confirmed by positive IFA testing. (Ex. 3, p. 95.) Although J.R.D.'s IFA testing was negative, the report also notes that "a negative [IFA] result does not rule out current mycoplasma pneumoniae infection as the specimen may have been collected prior to development of detectable antibody levels." (*Id.*)

Ultimately, Dr. Gans provides sufficient evidence to find that J.R.D.'s GBS was more likely than not caused by a factor unrelated to her vaccination, namely, a gastrointestinal or respiratory infection that she suffered one to two weeks prior to onset of her symptoms. Petitioners offer no substantive rebuttal to respondent's expert, and in fact only submitted a sparse report restating the pertinent facts from the medical record and concluding without any supporting explanation that J.R.D.'s vaccination may have contributed to her GBS. (*See* ECF No. 31.) Petitioners reported that J.R.D. experienced both flu-like symptoms and a GI infection prior to onset of her GBS symptoms, two factors that J.R.D.'s treating physicians and respondent's expert agree could have caused her GBS. (Ex. 2, p. 18, 67; Ex. 3, p. 550.) Taken together with Dr. Gans's unrebutted report, the record leads me to find that it is more likely than not that J.R.D.'s GBS was caused by a gastrointestinal or respiratory infection.

VI. Conclusion

Based on the foregoing, this case is hereby **DISMISSED**.[7]

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master

[7] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.